

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

ASTRAZENECA AB, AKTIEBOLAGET
HÄSSLE, ASTRAZENECA LP, KBI INC.,
and KBI-E INC.,

Plaintiffs and
Counterclaim-Defendants,
v.

HANMI USA, INC., HANMI
PHARMACEUTICAL CO., LTD., HANMI
FINE CHEMICAL CO., LTD, and HANMI
HOLDINGS CO., LTD.,

Defendants and
Counterclaim-Plaintiffs.

Civil Action No. 3:11-CV-00760-JAP-TJB

Judge Joel A. Pisano
Magistrate Judge Tonianne J. Bongiovanni

**DECLARATION OF PATRICK L. CHEN IN SUPPORT OF PLAINTIFFS' BRIEF IN
OPPOSITION TO HANMI'S MOTION *IN LIMINE* NO. 1 (TO PRECLUDE
TESTIMONY OF DR. WEISSINGER AND STRIKE HER EXPERT REPORT)**

I, Patrick L. Chen, hereby declare as follows,

1. I am an associate at the law firm of Fitzpatrick, Cella, Harper & Scinto, 1290 Avenue of the Americas, New York, New York 10104-3800, counsel for Plaintiffs AstraZeneca AB, Aktiebolaget Hässle, AstraZeneca LP, KBI Inc., and KBI-E Inc. in connection with the present action.

2. I make this Declaration on my personal knowledge in support of Plaintiffs' Brief in Opposition to Hanmi's Motion *in limine* No. 1 (To Preclude Testimony of Dr. Weissinger and Strike Her Expert Report).

3. Attached as Exhibit 1 is a true and correct copy of Hanmi's May 25, 2011 Initial Non-Infringement and Invalidity Contentions.

4. Attached as Exhibit 2 is a true and correct copy of AstraZeneca's July 25, 2011 Responses to Hanmi's Invalidity Contentions.

5. Attached as Exhibit 3 is a true and correct copy of Hanmi's December 9, 2011 First Amended Non-Infringement and Invalidity Contentions.

6. Attached as Exhibit 4 is a true and correct copy of Hanmi's January 30, 2013 Second Amended Non-Infringement and Invalidity Contentions.

7. Attached as Exhibit 5 is a true and correct copy of the February 19, 2013 Expert Report of Jerry L. Atwood, Ph.D.

8. Attached as Exhibit 6 is a true and correct copy of the April 8, 2013 Reply Expert Report of Jerry L. Atwood, Ph.D.

9. Attached as Exhibit 7 is a true and correct copy of the "Guideline for Submitting Supporting Documentation in Drug Applications for the Manufacture of Drug Substances" from the Center for Drug Evaluation and Research, FDA, dated February 1987.

10. Attached as Exhibit 8 is a true and correct copy of a 1989 article titled "The FDA Perspective on the Development of Stereoisomers" published in the journal Chirality by Wilson DeCamp.

11. Attached as Exhibit 9 is a true and correct copy of a 1989 article titled "Considerations in the Development of Stereoisomeric Drugs: FDA Viewpoint" published in the Drug Information Journal by Judi Weissinger.

12. Attached as Exhibit 10 is a true and correct copy of a document titled "FDA's Policy Statement for the Development of New Stereoisomeric Drugs" from the Center for Drug Evaluation and Research, Food and Drug Administration dated May 1992.

13. Attached as Exhibit 11 is a true and correct copy of the April 17, 2013 deposition of Dr. Paul A. Bartlett.

14. Attached as Exhibit 12 is a true and correct copy of literature produced by Hanmi on April 25, 2013.

15. Attached as Exhibit 13 is a true and correct copy of the April 24, 2013 Expert Report of Judi Weissinger, Ph.D.


16. Attached as Exhibit 14 is a true and correct copy of the April 26, 2013 deposition of Dr. Jerry L. Atwood.

17. Attached as Exhibit 15 is a true and correct copy of an email exchange between April 25 and April 28, 2013 regarding Dr. Weissinger's deposition.

18. Attached as Exhibit 16 is a true and correct copy of an email exchange between April 25 and April 28 regarding Dr. Weissinger's deposition.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: May 6, 2013



Patrick L. Chen